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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,165	04/16/2004	Jiro Kanie	889_001	8549
25191	7590	07/20/2006	EXAMINER	
BURR & BROWN PO BOX 7068 SYRACUSE, NY 13261-7068			YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/826,165	<b>Applicant(s)</b> KANIE, JIRO	
	<b>Examiner</b> Micah-Paul Young	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 May 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

**Acknowledgment of Papers Received:** Amendment/Response dated 5/11/06.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Ying et al (*Molded Rice Pudding with Chestnuts* recipe entry; *The New Good Housekeeping Cookbook*; 1986, pg. 542), Carlsson et al (USPN 5,716,639 hereafter '639) and Kabushiki et al (*Total Parenteral Nutritional and Enteral Nutrition*, page 283-307, Suppl. 5, *Nippon Rinsho*, vol. 59, no. 782). The claims are drawn to an enteral nutrient product and a method of production. The method comprises mixing the nutrient liquid and semi-solidifying agent in a holder other than the container and heat-treating the mixture.

4. The recipe calls for 3 whole eggs (semi-solidifying agent) to be mixed with 3 cups of milk (nutrient liquid) and other ingredients (step 2). The mixture is blended and added to another milk mixture and cooked in a saucepan (step 2). The combination is whipped and homogenized, then cooled (step 4). The product is an excellent source of calcium (nutritional information). The recipe however does not include agar as a thickening agent.

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5. The '639 patent teaches a lipophilic carrier preparation comprising agar and other nutrients in order to make cosmetic or food emulsions (abstracts). The aqueous solution used to make the emulsion of the invention comprises thickeners such as agar (col. 4, lin. 34-40). The formulation can be delivered orally, enteral or by any other means well known in the art (col. 5, lin. 8-11, lin. 25-32). The patent establishes the knowledge in the art of using agar as a thickening agent, in enteral emulsions.

6. The Kabushiki reference discloses an enteral feeding method for gastric catheterization and duodenum catheterization. The device administers thick fluid diets using tubing with diameters larger than 4 mm (diagram). The reference however does not disclose heat-treatment of the nutrient composition. A skilled artisan would be motivated to use the tubing of this device in order to deliver the nutritional product since the tube would be wide enough to support and allow even flow of thicker fluid diets.

7. With these things in mind it would have been obvious to include the agar of the '639 into the recipe of Ying into in order to improve the thickness of the pudding. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Also it would have been obvious to include either formulation into the tubing of Kabushiki in order to deliver a more stable enteral formulation. It would have been obvious to combine the emulsions with the feeding tube of the Kabushiki reference in order to deliver the enteral formulation directly to the intestine. It would have been obvious to combine the teachings and suggestions of

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the art with an expected result of an enteral formulation and delivery method for thicker nutritional emulsion.

***Response to Arguments***

8. Applicant's arguments filed 5/11/06 have been fully considered but they are not persuasive. Applicant argues that:

- a.* A skilled artisan would not use the formulations of the Ying reference as enteral formulations.
- b.* A skilled artisan would not be motivated to deliver the formulation of the Ying reference to a patient in need thereof.
- c.* There would no motivation to use the formulations for a patient in need since there are no concentrations in the prior art.

Regarding argument a., it is the position of the Examiner that due to the broad nature of the claims, it is the position of the Examiner that given the broadest reasonable interpretation of the claims the Rice pudding recipe meets the limitations of the claims. The claims require a self-sustaining composition comprising a nutritional fluid and a thickening agent identified as an egg. The intended use of the composition is for enteral delivery, however applicant is reminded that where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). The prior art provides a nutritional formulation comprising a nutritional liquid and a thickening

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agent that is self-sustaining. Since these are the only requirements of the claims, they remain obviated by the art.

Regarding argument b., the '639 and Kabushiki references disclose enteral formulations and devices. Though these do not explicitly state the patient suffer from dysphagia, the fact that enteral formulations are disclosed suggests that any patient in need of a feeding tube device and enteral formulation would indeed have some sort of eating disorder, or difficulty swallowing. The '639 patent discloses enteral formulations comprising agar and nutritional liquids while Kabushiki discloses a device for enteral formulations. These inventions can only be used for the delivery of compositions enterally to those with problems eating or swallowing. Their treatment of those suffering from dysphagia would be inherent to these inventions. For these reasons the claims remain obviated.

Regarding argument c., applicant is directed to the Ying recipe, which calls for 3 whole eggs and 3 cups of milk. This is equivalent to approximately 1 egg per 240 mL of milk, well within optimizable ranges for a nutritional composition. Further the ranges are not presented in the broadest claim since they only require eggs or agar and a nutritional liquid. It would be well within the level of skill in the art to optimize the ranges and concentrations through routine experimentation in order to customize the enteral formulation. For these reasons at least the claims remain obviated.

***Response to Amendment***

9. The Affidavit filed on 5/11/06 under 37 CFR 1.131 has been considered but is ineffective to overcome the combination of the Ying, '639 patent and Kabushiki references. There are no comparisons between the combinations of the prior art directly. The Affidavit discloses the effectiveness of the instant invention, yet the effectiveness is not in question. The obviousness of the invention is. It remains the position of the Examiner that it would have been obvious to include either the recipe of Ying or the enteral formulation the '639 patent into the device as described by Kabushiki since all that is required of the delivered formulation is a nutritional liquid, and egg or agar and a consistency that is self sustaining. For these reason at least the affidavits are ineffective and the claims remain obviated.

***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608.

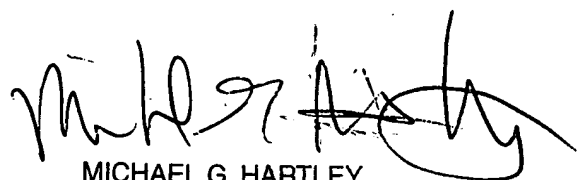
The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER